

Submitting or Requesting an NDC Labeler Code in SPL Format

SPL Release Four Training Session – Module 1

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SPL R4 2009 Winter/Spring Training Session Schedule

- Session 1 – February 4, 2009 – March 11, 2009, Web Conferences
- Session 2 – March 18, 2009 – April 22, 2009, Web conferences
- Session 3 - May 21, 2009, Face-to-Face – Rockville, MD, Parklawn Conference Room D, 9:30 a.m. – 3:30 p.m.
- Session 4 – February 5, 2009 – March 12, 2009
- Session 5 – March 19, 2009 – April 23, 2009

Transition from Paper to Electronic Drug Establishment Registration & Drug Listing

- Changes in FD&C Act require electronic registration of drug establishments and listing of human prescription drugs, OTC, animal drug, biologic products – September 2007
- Draft Guidance document for electronic drug establishment registration and listing – July 2008
- FDA is adopting the use of extensible markup language (XML) files in SPL format as the standard format for the exchange of drug establishment registration and drug listing information.

Transitioning from Paper to Electronic: Drug Registration and Listing

- If you electronically list your product(s) do not list the same product(s) using paper (FDA Form 2657 or FDA Form 2658)
- If you register your drug establishment(s) electronically, do not register the same drug establishment(s) using the paper (FDA Form 2656)

Introduction to SPL

The Standard:

Structured Product Labeling (SPL)

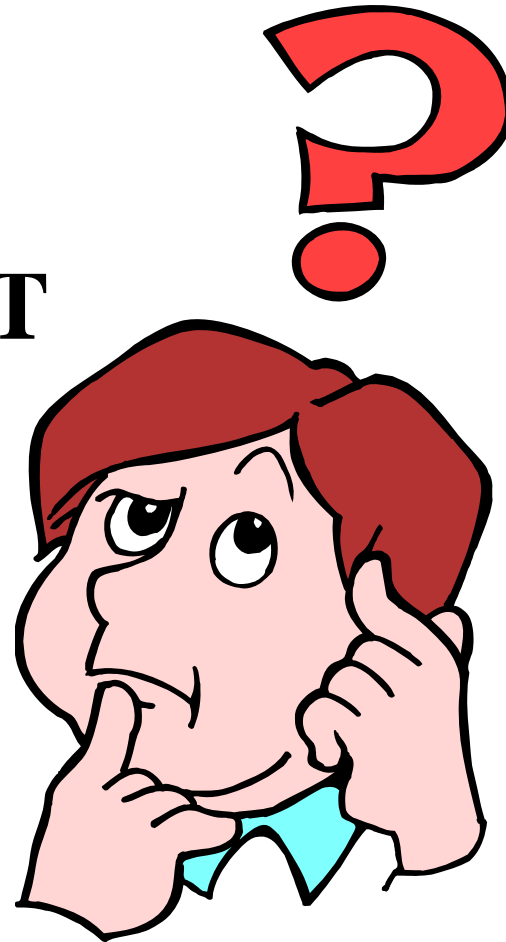
SPL Standard

- The Structured Product Labeling (SPL) is a document markup standard approved by Health Level Seven (HL7) and adopted by FDA as a mechanism for exchanging product information.
- American National Standards Institute (ANSI) accredited (SPL Release 3) – June 2007
- SPL is created using **EX**tensible **M**arkup **L**anguage

XML & XSL Stylesheet

- XML – **EX**tensible **M**arkup **L**anguage
 - Relatively human-legible
 - Machine readable
 - Tags (elements) permit search of key information
- XML Documents – created via Notepad, Word Pad, XML validation tools, Xforms, etc...
- XSL Stylesheet – transforms the XML data to be viewed via web browser or printed documents

**WHY CHANGE
THE DRUG LISTING
AND ESTABLISHMENT
REGISTRATION
PROCESS THAT HAS
WORKED FOR
DECADES ????**



This is a detailed regulatory form, possibly an FDA Form 3606, used for submitting information about a medical device. It includes sections for:

- Device Identification
- Manufacturer Information
- Device Description
- Intended Use
- Device Classification
- Device History
- Device Performance
- Device Safety
- Device Effectiveness
- Device Compliance
- Device Approval

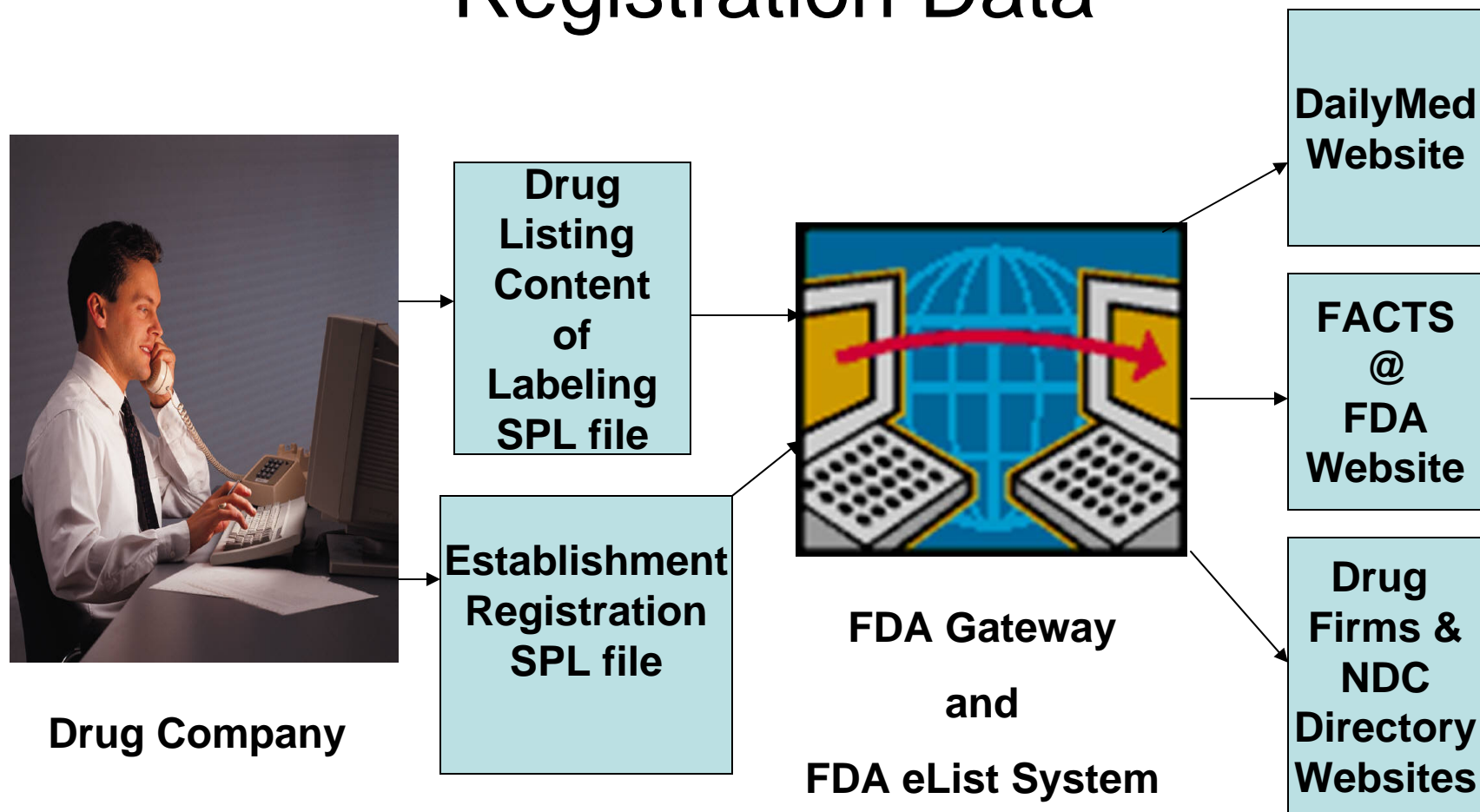
 The form contains numerous checkboxes, text boxes, and a large table at the bottom for detailed data entry.

This form features a large table with multiple columns and rows, designed for structured data entry. The table has several headers and sub-headers, and the rows are organized into distinct sections. This layout is typical for forms used to track multiple instances of a process or to report on various data points over time.

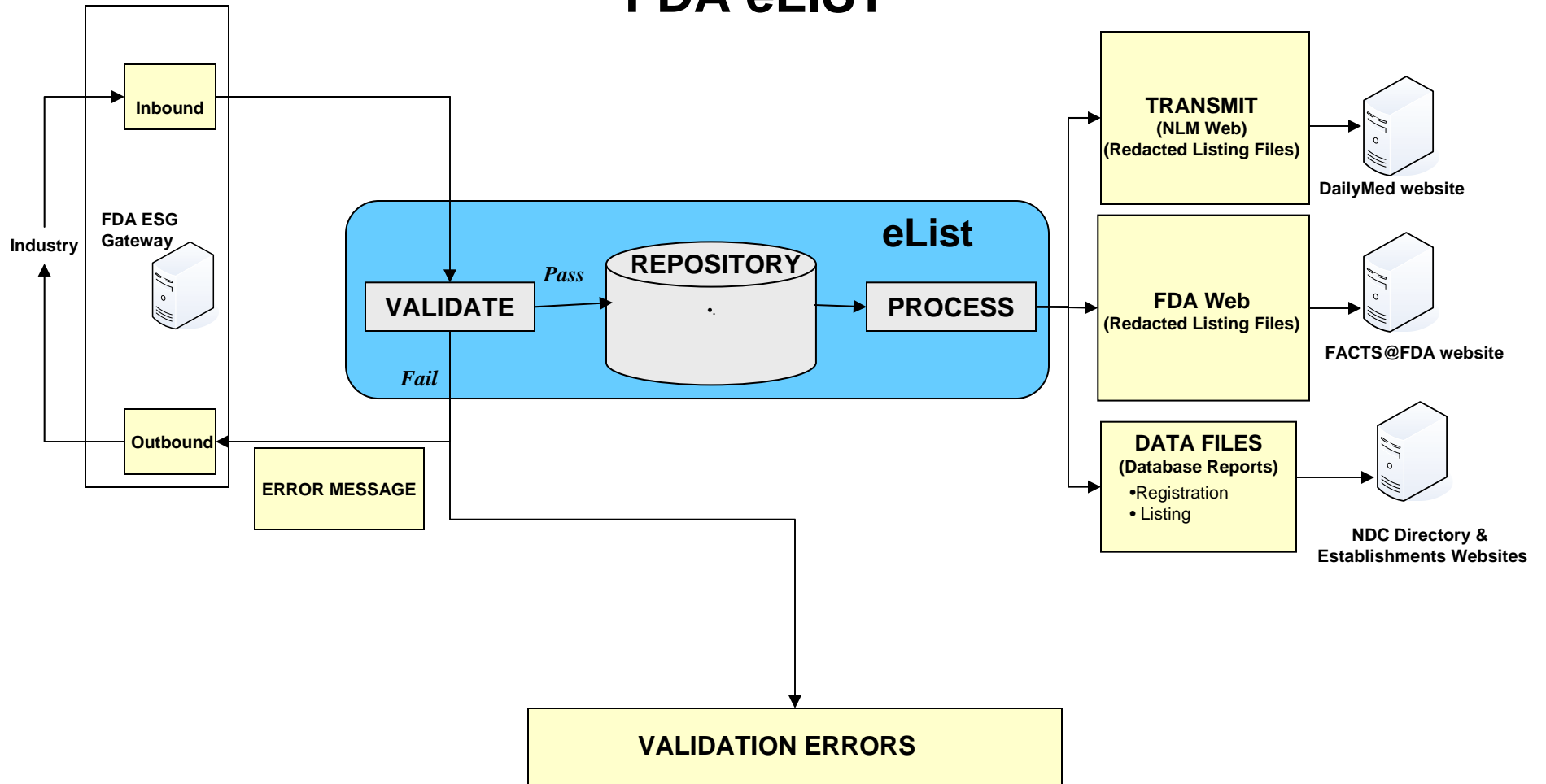
This form is another example of a structured data entry form, featuring a large table with multiple columns and rows. It includes various headers and sub-headers, and the rows are organized into distinct sections. This layout is typical for forms used to track multiple instances of a process or to report on various data points over time.

- Eliminate duplicative and redundant data entry
- Eliminate paper submissions
- Automate processing of data in a submission type in electronic format in a manner that FDA can adequately process, review, and archive.

You Control the Published Electronic Drug Listing and Establishment Registration Data



FDA eLIST



...three e-Files for Registration & Listing – SPL Format

- NDC Labeler Code Request
- Establishment Registration
- Content of labeling (CoL)/Listing

Order of Submissions

1. NDC Labeler Request (LCR) and Establishment Registration (ER) SPL
 2. CoL/Listing SPL
- CoL/Listing validates against data submitted in NDC LCR and ER SPL

Administrative (Document Tracking Information)

Basic information to identify the SPL document:

- **Document ID:** is a Globally Unique Identifier (GUID) and is unique for each version of the document. Letters used in a GUID are lower case.
- **Document Type:** The `<code>` is the LOINC code which provides information on the document type.
- **Effective Time:** provides a date reference to the SPL version including the year, month and day as yyyyymmdd.
- **SetID:** is a GUID and is a unique identifier for the document that remains constant through all versions/revisions of the document.
- **Version number:** is an integer greater than zero that provides a sequence to the versions of the document.

NDC Labeler Code Request Data

- **Document Information**

- Type of document
- ID
- Set ID
- Version Number
- Effective Time

- **Labeler**

- Name
- DUNS Number
- NDC Labeler Code

- **Contact**

- Name
- Mailing Address
- City
- State
- Country
- Postal Code
- Telephone Number
- Email Address

NDC Labeler Code Request Xforms View

HL7 SPL - NDC Labeler Code Request v 0.71	
<div>Open Save As Save</div>	
<div>NDC Labeler Code Request Preview</div>	
Document Information	
Type of document	NDC LABELER CODE REQUEST
ID	3267a844-378f-4020-912b-43babb77001d
Set ID	8d24aab5-8f91-42ca-9637-997a3d223e5c
Version Number	1
Effective Time	20080909
example(YYYYMMDD)	
Labeler	
Name	Acme Pharmaceuticals, Inc
DUNS Number	111119999
NDC Labeler Code	44444
<div>Add NDC Labeler Code Delete NDC Labeler Code</div>	
Contact	
Name	Charles Daniels
Mailing Address	44 Pembroke Drive
City	Rockville
State	MD
Country	USA
Postal Code	20888
Telephone Number	tel:+1-888-888-4757
Email Address	mailto:charles.daniels@acme-pharmaceuticals
example(tel:+1-201-555-1212) example(mailto:xportal@globalsubmit.com)	

NDC Labeler Code Request SPL Document

Acme Pharmaceuticals, Inc

Product Information	
Product Type	NDC LABELER CODE REQUEST

Labeler - Acme Pharmaceuticals, Inc (111119999) **NDC Labeler Code:** 44444

Contact	Address	Telephone Number	Email Address
Charles Daniels	Address: 44 Pembroke Drive City, State, Zip: Rockville , MD, 20888 Country: USA	+1-888-888-4757	charles.daniels@acme-pharmaceuticals.com

Revised: 09/2008

Acme Pharmaceuticals, Inc

NDC LCR SPL Scenarios

- **Requesting a new NDC Labeler Code**
 - Fill out the *NDC Labeler Code request* as described in sections 2.1 through 2.4 leaving the NDC Labeler Code field empty.
 - Requests for NDC Labeler Codes are individually evaluated prior to entry into the NDC System. The initial request will be automatically stopped because there is no NDC Labeler Code provided and is diverted to a FDA reviewer. Once the evaluation is completed, the response to the request is directed to the designated contact person.
 - Once the NDC Labeler Code is assigned, open the original SPL file and add the newly assigned NDC Labeler Code and resubmit the corrected file.
- **Initial electronic submission when NDC Labeler Code already assigned**
 - Fill out the *NDC Labeler Code request*. Only one NDC Labeler Code is included in an SPL file. In other words, use a different setId root for each NDC Labeler Code request.

NDC LCR SPL

Scenarios cont...

- **Correct SPL file validation error**
 - If an SPL file cannot be processed because of a validation error, a report on the validation error is sent from FDA to the contact person. Open the SPL file and correct the errors.
- **Correct a mistake in an SPL file just submitted**
 - Open the SPL file, correct the mistake, and fill in a **new id root** and **new version number** with the **original setId root** and the appropriate effective time.

NDC LCR SPL

Scenarios cont...

- **Update the NDC Labeler Code information**
 - Open the previous SPL file and fill in the new information without changing the other existing information. Fill in a **new id root** and **new version number** with the **original setld root** and the appropriate effective time.
- **Requesting a second NDC Labeler Code**
 - Only one NDC Labeler Code is associated with each *NDC Labeler Code request*. If a second NDC Labeler Code is requested, fill out a separate SPL file with a **different setld root**. The labeler information and contact information is the same as the SPL file for the first NDC Labeler Code request

Notes

- Use NDC Labeler Code used in NDC Package Code (3-segment NDC)
- Submit NDC labeler codes that are used in NDCs associated with distributed products. (NDC on packaging)
- Only one NDC labeler code per NDC Labeler Code Request.
- NDC Labeler Code – Code should be identical to first segment of NDC (no leading zeros)

Next Module

- Establishment Registration – Domestic Establishments

QUESTIONS